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2. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS per 21 CFR 807.92

General Company Information

Name: Ivera Medical Corporation
Contact: Don Canal
Vice President RAQA

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San Diego, Ca 92130
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Date Prepared: September 29, 2008

General Device Description

The CuroTMs Port Protector device is a single use, non-sterile device that contains 70% Isopropyl Alcohol and is intended to be used to decontaminate needleless luer activated valves.

Product Name: CuroTMs Port Protector
Classification: Unclassified Device under product Code LKB

Predicate Devices

K833182 APLICARE Alcohol Prep Pad

Intended Use (Indications)

The CuroTMs Port Protector is a device containing 70% Isopropyl alcohol. When left in place for 5 to 15 minutes the CuroTMs Port Protector decontaminates the injection port; thereafter the CuroTMs Port Protector provides a physical barrier during the intended use.

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Substantial Equivalence

Ivera medical has provided performance test data to satisfy the requirements of a decontaminating device by reducing the bacterial count two (2) selected gram positive bacteria and 2 selected gram negative bacteria. Ivera Medical also demonstrated equivalence to the predicate device with comparison test data.

The data presented demonstrate that the device is substantially equivalent to the Predicate Device and is suitable for its indicated use.

Conclusions

The test results and analysis of data demonstrate the **Curos™** Port Protector is substantially equivalent to the predicate devices with comparison data.



OCT 21 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Donald Canal
Vice President Regulatory Affairs and Quality Assurance
Ivera Medical Corporation
3525 Del Mar Heights Suite # 430
San Diego, California 92130

Re: K080466
Trade/Device Name: CuroTM Port Protector
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKB
Dated: September 30, 2008
Received: October 2, 2008

Dear Mr. Canal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Indications for Use

K080466

Device Name: The CUROS™ Port Protector

Indications For Use:

The CuroS™ Port Protector is a device containing 70% Isopropyl alcohol. When left in place for 5 to 15 minutes the CuroS™ Port Protector decontaminates the injection port; thereafter the CuroS™ Port Protector provides a physical barrier during the intended use.

Prescription Use ☒

AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 080466